



Top Ten Things to Know About the HIPAA Privacy Rule for Research

1. The HIPAA Privacy Rule does not change the Common Rule

The Common Rule is the primary governing rule for the ethical conduct of research. The Privacy Rule applies to the protection of personal information; the Common Rule applies to the protection of human subjects in research.

2. The Privacy Rule does not distinguish between types of research

Research is more than just clinical trials; application of the provisions of the Privacy Rule may vary depending on the type of research being conducted.

3. HIPAA is more than just Privacy; Privacy is more than just HIPAA

Administrative Simplification provisions of HIPAA include standard transactions and code sets (an IT concern), identifiers, security and privacy. In addition to the HIPAA Privacy Rule, VHA is subject to at least five other, pre-HIPAA federal laws relating to privacy of medical information.

4. VHA policy may conflict with affiliate policy

General policies in each institution may be the same but specific procedures may differ; work closely with the affiliate to work out the differences.

5. VHA is one covered entity for purposes of the Privacy Rule

Each facility is not an independent covered entity.

6. Research conducted within VHA is a USE, not a DISCLOSURE

Very important for accounting/tracking purposes: accounting requirement applies to disclosures only.

7. Study sponsors generally are not business associates

No need for a business associate agreement, however, transfers of information to the sponsor are disclosures and must be tracked for accounting, UNLESS an exception applies (FDA requirement, Authorization, Limited Data Set).

8. Researchers may use a "limited data set" or "de-identified data"

De-identification requires the removal of 18 data elements (not just name, SSN); a limited data set contains more information and is available only for three purposes: research, public health activities and health care operations.

9. Waivers or Alterations of Authorization are allowed ONLY for Research

May be granted only by an IRB or Privacy Board upon findings mandated in the Privacy Rule.

10. Researchers may use or disclose PHI without authorization in limited circumstances

A researcher may use PHI to prepare a protocol or may use decedents' information without prior authorization (or waiver of authorization from an IRB or Privacy Board) under conditions described in the Privacy Rule.

FOR MORE INFORMATION ABOUT IMPLEMENTING THE HIPAA PRIVACY RULE IN RESEARCH, CONTACT PATRICIA LYNCH WATTS, J.D., Office of Research and Development, 202-254-0281, or patricia.l.watts@hq.med.va.gov.